Patent Application No.: 09/919,275

Finality of Office Action is Premature

With respect to the rejection of claims 16-18 and 20-21, Applicants respectfully maintain that the finality of the present Office Action is premature as the Examiner has introduced new grounds for rejection not necessitated by amendment (the rejected claims being in original form). As set forth in more detail below, Applicants request acknowledgement of this fact and that Applicants be permitted to further respond, or to enter amendments as of right, in the event the rejection is maintained with an alternative to Kehr (after the earliest priority date of the present application).

As noted previously, the claims of the instant application are distinguishable from other medical diagnostic systems that simply seek a set of symptoms and input the symptoms to an artificial-intelligence engine to create a definitive diagnosis. Wilk and Bodick do not address the essential challenge of a visual diagnostic process; perception and recognition of visual variants. Tolerating the ambiguity of paradoxical visual and non-visual clues and the uncertainty inherent to medicine and the biologic diagnosis and recognition is an essential feature of this application as set forth at pages 2 and 3 thereof.

Turning now, to the office action, claims 1-15, 19, 22-24 and 28 were rejected under 35 USC §103(a) as being unpatentable over US 5,437,278 to Wilk (Wilk) in view of US 4,945,476 to Bodick et al. (Bodick). Claims 16-18 and 20-21 were newly rejected under 35 USC §103(a) as being unpatentable over Wilk in view of Bodick and further in view of US Application 2003/0036683A1 to Kehr et al. (Kehr).

The disclosures of the cited art and the distinctions between claims 1 – 24 and 28 may be briefly summarized as follows:

The disclosures of Wilk and Bodick are directed to automated medical diagnosis. Applicants respectfully contend that the inherent ambiguity of medical diagnosis requires not automated diagnosis, but a knowledge presentation facilitating rapid comparison and perception by the user - an essential distinction set forth in the claims. The ability of the human eye to make visual comparisons between thousands of possibilities is impossible, yet when choices are constrained to a few, recognition is near instantaneous. The purposeful design of the claimed system and method in the instant application combines medically relevant knowledge to filter the search to a manageable number of diagnostic possibilities. This combination of a

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medical knowledge base interwoven with visual input display is not described in Wilk, Bodick or any other patent application. While there may be decision support systems used in human medicine, none support presentation of visual knowledge, and certainly none allow for the display of visual complexity, contextualized to the user search as recited in the current claims.

Wilk discloses a medical diagnostic system described as having a device 20 for monitoring and measuring a biological or physiological parameter, transmitting the parameters to a computer 24, and ultimately communicating a medical diagnosis as determined by the computer. As set forth at col. 3, lines 58 – 63, "[b]ecause diagnoses are made by computer in accordance with the present invention, it is frequently unnecessary to have a doctor present during data taking (symptom recording and measurement) and communication of the diagnosis to the patient." At col. 5, lines 30-31, Wilk suggests a video camera for obtaining an image of a portion of a patient's skin. And, as noted by the Examiner, Wilk suggests use of the system for dermatological diagnosis wherein images of skin conditions are stored (col. 2, lines 46-56 and col. 6, lines 17-21).

Wilk is clearly directed to an automated medical diagnostic system (e.g., col. 3, lines 51-52), where the "diagnoses are made by computer" (col. 3, line 58). Whereas the claimed system recognizes the inherent problems with computer diagnostic systems and is intended, as recited in the preamble, to aid in the diagnostic process – not as a substitute for a medical professional's diagnosis, but to visually assist such a professional with the diagnosis.

Applicants further contend that Wilk's automated diagnostic system teaches away from the system to aid in a visual diagnostic process as recited by the rejected claims. Applicants urge that there is no teaching in Wilk of the use of monitor 74 for other than communicating diagnostic results (col. 6, lines 52-53). This distinction is further emphasized by the systems and methods recited in the independent claims – which do not require the uploading or transmission of image data for computer analysis, but rely on the user's visual comparison, of previously stored images (image database) in conjunction with a subset of possible diagnoses, to that which is observed by the user.

In reply the Examiner has stated that "it would have been obvious that a medical professional would have used the systems of Wilk and Bodick as an aid rather than a

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substitute for a diagnosis." Applicant not only disagrees, but respectfully contends that the Examiner has failed to provide any support for such a position. Although Wilk suggests that a physician may confirm the diagnosis (col. 3, line 64-65), Applicants urge that this is not a suggestion of using the Wilk system as a diagnostic aid.

While Wilk does disclose the storage of images, it does not disclose the storage of images in an image database, separate from a knowledgebase, nor the cross-referencing of the image database with the knowledgebase for purposes of assisting in the diagnostic process as recited in the rejected independent claims (e.g., claims 1, 3, 5 and 28). Applicants review of Wilk, both in the locations referenced and in its entirety, did not identify any reference to a database, or separate image and knowledge databases. Rather, what was found was reference to bulk storage and memory (e.g., 28 in Fig. 1), which do not teach the recited image database and knowledgebase.

Similarly, Applicants review of Wilk, particularly at columns 4 and 7, fails to identify a user interface to "solicit ... a plurality of descriptive characteristics of a sample requiring diagnoses" and use of such characteristics to automatically identify a subset of diagnoses as recited in amended claim 1. Although Wilk does describe a keyboard used for entry of information identifying the patient (col. 4, lines 50-51), it would be absurd to ascribe to such teaching support for "solicit[ing], from a user, a plurality of descriptive characteristics of a sample requiring diagnoses," as recited in claim 1. To view such a teaching in the manner urged in the rejection would be to suggest that a diagnosis may be determined by simply inputting information to identify a patient. Wilk clearly teaches that it is devices 20 (thermometer, blood pressure gauge, etc. as described at col. 4, lines 32-39) that provide the information upon which a diagnosis is determined – which would not be understood to be the user's input.

As the Examiner has acknowledged, Wilk also fails to disclose identifying a subset of diagnoses and use of the subset to reorganize the information space of the image database, as required by the rejected claims. In fact, it is not clear that Wilk teaches or suggests the display of any images to the user.

Bodick teaches the creation of a knowledge base containing both pictorial images and textual information therein (col. 2, lines 39-40), along with a system to use such

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information in a medical diagnosis. The system is further described as being dynamic; to permit the addition of newly discovered characteristics observed in patients and deletion of characteristics having little diagnostic importance. As Bodick points out, the disclosed knowledge base is distinct from a classic database (col. 3, lines 12-16).

Although Bodick does describe alternative methods of accessing the knowledge base (by cases having specific features or by cases in which a particular disease was diagnosed; col. 5, lines 42-48), Applicants respectfully submit that such a teaching does not give rise to the recited limitations of "automatically identify[ing], from a plurality of possible diagnoses, a subset including a plurality of diagnoses that are consistent with the characteristics." It is also important to note that Bodick and Wilk both appear to presuppose that there is always a diagnostic answer, when in fact there is often no definitive answer in human medicine.

With regard to the further limitation of "automatically reorganizing an information space of said image database for concurrent presentation of a plurality of images for user review," Applicants respectfully submit that no such teaching is found in Bodick, and that Bodick, in fact, teaches away from such a limitation. For example, at col. 2, lines 59-61, where a comparison is described between "one patient or sample" and a "previous patient or sample" there is a strong implication that only a single representation is displayed at one time. Similarly, col. 6, lines 19-22 of Bodick clearly indicate that information from a single record is displayed – not concurrent display of a plurality of images reflecting a subset of diagnoses as recited in the rejected claims (e.g., claim 1).

As to the basis for the alleged combination, the Examiner urges that it would have been obvious to modify Wilk to incorporate searching and image display as taught by Bodick. Applicants challenged this basis, and in response the Examiner has indicated that Wilk is interpreted as disclosing an aid to diagnosis. As noted above, this is a mischaracterization of Wilk, which is directed to a "medical diagnostic system" (col. 4, line 29), where the relationship to a physician is stated as "eventually sees a physician for confirming the diagnosis" (col. 3, lines 64-65), and not as an aid. Automated diagnostic systems, such as disclosed by Wilk, are not designed to assist a user in diagnosis or the critical need to tolerate the ambiguity and complexity of medical diagnosis. Applicant respectfully stresses this distinction and the purposeful

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design of the claimed invention to aide recognition within the context of the inherent variation of human nature.

It also remains unclear what would have motivated one skilled in the art to modify Wilk's automated medical diagnostic system to make it "unautomated" and used for searching of case data. No motivation is found in Bodick to suggest making Wilk's automated diagnostic system a manual system. Accordingly, Applicants respectfully urge that the various statements of Bodick and Wilk would suggest that the teachings were not combinable, and certainly do not support the proposed modification of Wilk. In light of such teachings, Applicants respectfully urge that the modification of Wilk in view of Bodick is not supported by the references themselves, and was motivated solely by the limitations of the rejected claims, used as a "recipe" to select unrelated elements of the different patents. Accordingly, the rejection is traversed and claims 1, 3, 5 and 28 are respectfully urged to be in condition for allowance.

Considering, *in arguendo*, the combination of Wilk in view of Bodick, at most such a combination teaches the use of a common collection of data or knowledge, for an automated medical diagnostic system. The modifications suggested by Bodick (with arguments to the contrary presented above) would at most suggest that data of the Wilk system may be searched and text and/or an image from a case displayed to a user of the system as suggested by Bodick. Such a combination or modification does not, however, give rise to a user interface to solicit a plurality of descriptive characteristics of a sample requiring diagnosis as recited in claim 1. And, as noted above, neither Wilk nor Bodick teach the automated identification of a subset having a plurality of diagnoses, in response to characteristics. To assure proper consideration of these limitations, Applicants direct the Examiner's attention to pages 25 – 28 of the specification, and Figures 12 and 14, which describe and illustrate the response of the present invention to additional characteristics and the reordering of the information space (note the change in ordering of images/diagnoses in response to the addition of the "obesity" characteristic in window 292). Rather, the arguable combination teaches, at most, the manual searching of case records, and as suggested by Bodick, the display of images and text associated with the case record. Applicants respectfully submit that neither reference teaches the automatic reordering of an information space and concurrent presentation of a plurality of images for user review, as recited in independent claims 1, 3, 5 and 28, and the claims are, therefore, patentably distinguishable over the arguable combination.

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With regard to claims 2 and 4, Applicants hereby incorporate the arguments set forth above relative to the independent claims, and further urge that the Examiner has mischaracterized the search capability of Bodick. Claims 2 and 4 recite automatically reorganizing the information space in response to a user's modification of a descriptive characteristic. The recited feature is depicted, for example, in Figures 7 and 8 and described at page 24 of the as-filed application – where a user's selection of a descriptive characteristic results in the alteration of the images displayed. No such teaching has been identified or illustrated in Bodick. With due respect to the Examiner, the Bodick disclosure of permitting an expert to compare observations (col. 2, line 55), designate diagnostic features (col. 5, line 54) or the ability to modify a category name (col. 20, lines 4 – 6), does not teach or suggest reorganizing the information space upon modification of at least one of the plurality of descriptive characteristics by the user. Accordingly, Applicants respectfully traverse the rejection and urge that claims 2 and 4 are, therefore, patentably distinguishable over the arguable combination of Wilk in view of Bodick.

With regard to claim 5, Applicants again incorporate the various arguments set forth above with respect to claims 1 and 3. In particular, Applicants respectfully maintain that Wilk discloses an automated medical diagnostic system, whereas claim 5 recognizes the inherent problems with such systems and is intended, as recited in the preamble, to reduce diagnostic uncertainty – not as a substitute for a medical professional's diagnosis. Applicants respectfully contend that Wilk's automated diagnostic system teaches away from the visual aid system characterized by claim 5. While Wilk does disclose the storage of images, it does not disclose the recited user interface, the storage of images in an image database, separate from a cross-referenced knowledgebase, let alone the acknowledged failure to disclose or suggest the automatic reorganization of an information space and concurrent presentation of images for user review. As previously noted, the summary from pages 2 and 3 of the specification supports the position that the claimed invention is directed to the ability to provide a visual aid to a diagnosis, while not dictating or determining a diagnosis (as taught by Wilk). Both Wilk and Bodick fail to address a solution for diagnosing when there are thousands of variations and images that are at the core of medical diagnosis and the biologic world.

Bodick teaches the creation of a knowledge base containing both pictorial images and textual information therein (col. 2, lines 39-40), along with a system to use such

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information in medical diagnosis. Like Wilk, however, Bodick also fails to teach or suggest the automatic identification of a subset including a plurality of diagnoses, and then using the subset, automatically reorganizing the information space to provide for its presentation to the user – using concurrent presentation of multiple images for review. Absent a teaching relative to the recited identification of a plurality of diagnoses, and the automated reorganization of the information space in an image database for concurrent presentation of images (specifically recited in claim 5), *prima facie* obviousness has not been established. Accordingly the rejection is traversed and claim 5, and all claims dependent therefrom, are respectfully urged to be patentably distinguishable over the arguable combination of Wilk in view of Bodick.

Turning to the rejection of claims 6 – 11, the Examiner acknowledges that Wilk fails to teach an image stack, yet maintains that Bodick discloses a diagnostic image stack, as recited in the rejected claims, by disclosure of a diagnostic tree in Fig. 26. The Examiner is referred to Figures 8 and 12-15 of the instant application, and the associated description at pages 24 – 25 of the Specification. Applicants further refer to page 29 of the instant application, where lines 13 - 29 state:

> "Users are able to view a results in the "contact sheet" format such as is depicted in Figures 8, 12 and 14, which include reduced-size image thumbnails in stacks, grouped by diagnosis. This interface represents one of the core functionalities of the present invention. As contrasted to a simple image database or image atlas, the diagnostic grouping of thumbnails allows the user to visually scan and review images in the context of diagnostic possibilities. Each diagnostic "stack" may also allow for a set of controls that permit the user to sort the images in the "stacks" by body location (this facilitates comparison of like lesions between diagnoses), "spread" out the stacked thumbnails so all thumbnails for a particular diagnosis can be viewed in a separate window (e.g., Figure 9), and display the related findings for the diagnosis. Thumbnails will also be easily exploded into full screen images at a mouse click such as depicted on screen 352 in Figure 15. It is also contemplated, in accordance with the image display, that the diagnostic image stack may be organized for display to depict a natural progression through stages of disease progression."

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Applicants respectfully maintain that Bodick is clear as to the contents of Figure 26. At col. 9, line 22, Figure 26 is described as "a display used in selecting a diagnosis tree" and at col. 21, lines 18 – 29, as "an example of an existing diagnosis tree." Applicants are simply unable to determine where in Figure 26 the Examiner is able to see a "diagnostic image" let alone the recited "diagnostic image stack." Figure 26 does disclose various nodes of a diagnostic tree for editing, and the "[d]iagnoses are listed in a hierarchy, and the selection by the user of any diagnosis included in the displayed list results in a list of next lower level diagnoses, the selection of any one of which results in yet another list of a still lower level of diagnoses, and so on" (col. 17, lines 44 – 48). These sequential levels of diagnoses indicate the dependence of a given diagnosis on the preceding higher levels of diagnoses. Bodick's design premise is the ordering and display of diagnoses within a hierarchical "tree". A hierarchical "tree" structure is an entirely different information strategy from the overlapping, Venn functionality offered by the recited image stack of application, and more particularly "wherein the index is independent of the common diagnosis" as recited in claim 7. The present invention allows the user to enter multiple parameters which then result in diagnoses displayed by a number of matches. Dependent upon user morphologic images, diagnostic images sort to the top of diagnostic stacks. The ability of the user to visually, scan and compare diagnoses along two axes simultaneously, diagnostic matches and morphologic matches aides comparison and anticipates the need to assist perception and recognition within the context of ambiguity.

A hierarchical display of diagnoses simply does not allow for the flexible display of diagnoses in image stacks as recited in the present claims. Bodick does not teach the display of a diagnostic image stack as the term is used herein. Furthermore, as noted by the Examiner, Bodick also fails to disclose the alteration of the image stack in accordance with disease progression (claim 8). In addition to the above-noted distinctions, Applicants reiterate that claims 6 – 11 depend from presumably allowable claim 5. Accordingly, Applicants respectfully traverse the rejection and submit that claims 6 – 11 are patentably distinguishable over the arguable combination of Wilk in view of Bodick.

With regard to claim 12, in addition to being dependent from presumably allowable claim 5, claim 12 further recites using characteristics of diagnoses, solicited via the user interface, to perform pattern recognition and identify diagnoses with matching

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characteristics. On the other hand, Wilk teaches the comparison of digitized data from monitoring/measuring device 20 for purposes of deriving a diagnosis of the patient's condition. Thus, Wilk cannot teach what has been alleged; as to do so would require a user-interface for entry of characteristics observed by a user that are not taught or suggested by Wilk. As noted previously, the Wilk user interface is not described as facilitating the entry of diagnostic characteristics. Thus, Applicants urge that in addition to being dependent from allowable claim 5, claim 12 is itself patentably distinguishable over the arguable combination of Wilk in view of Bodick.

With regard to claims 13-14 and 15, Applicants once again urge that these claims are patentably distinguishable over the arguable combination for the reasons set forth above relative to claim 5. Moreover, while acknowledging that Wilk suggests use of the automated medical diagnostic system for dermatological diagnosis, there is no suggestion that such diseases must be of a type having visual findings visible to an unaided human eye or require mechanical examination — the latter being of some question as to how it may be performed by an automated system. It appears, the diagnostic input employed by Wilk system is obtained from the described devices or possibly the video camera. Hence, claims 13 – 15 are respectfully urged to be patentably distinguishable over the arguable combination of Wilk in view of Bodick.

Considering claims 19 and 22-23, each of these claims includes limitations relative to alternative uses of the system of claim 5. The Examiner acknowledges that Wilk and Bodick both fail to teach the alternative applications set forth in claims 19 and 22-23. Nonetheless, the rejection urges that Bodick's suggestion of the use of image data is somehow a teaching of such limitations. Absent a teaching or suggestion of the claimed limitation, obviousness cannot be established. In the event the Examiner is relying on an additional reference, Applicants request that the rejection set forth the reference. Otherwise, Applicants traverse the rejection and maintain that the Examiner has failed to establish *prima facie* obviousness to which a response can or must be supplied. Applicants respectfully request that claims 19 and 22-23 be indicated as allowable in a subsequent action.

Relative to claim 28, Applicants arguments in the immediately preceding paragraph are further applicable to the rejection of this independent claim. In setting forth the rejection, the Examiner has failed to establish where each of the recited limitations is taught or suggested by the references relied upon — either alone or in combination.

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In particular, the Examiner acknowledges that none of the references of record is described as providing assistance in investigating a cause of death, nor are particular characteristics as to a manner of death, wound type, modality, etc. taught or suggested either by Wilk or Bodick. However, as in the rejection of claims 19 and 22-23, the Examiner nonetheless asserts that Bodick teaches the importance of using images and text "in any area where the appearance of an object under study/examination is of critical importance" as taught by Bodick at col. 9, lines 47-50. However, even if Bodick might be extended in the manner proposed by the Examiner, such an extension does not give rise to a basis for the rejection – nor does it teach the specific limitations set forth in a manner so as to have rendered it obvious to one of skill in the art at the time of the invention - particularly when the rejected claim recites specific limitations not found in the references. Applicants respectfully traverse the rejection of claim 28 and contend that *prima facie* obviousness has not been established so as to require or permit a further response.

With regard to the new rejection of claims 16-18 and 20-21, Applicants previously acknowledged the Examiner's Official Notice as to use of icons. However, even if use of icons was known at the time of the invention, their use in the manner recited in the rejected claims was urged to be unknown and non-obvious. Moreover, the Official Notice was in conjunction with Wilk and Bodick, yet the Examiner did not indicate where the motivation for making use of icons was taught or suggested by either Wilk or Bodick.

Moreover, Applicants' position was that Wilk needs no such icons as it is not a diagnostic aid, but an automated medical diagnostic system. Similarly, Bodick fails to suggest use of icons, and does not appear to teach or suggest the particular manner in which rejected claims 16-18 and 20-21 use such icons (e.g., symptoms represented as icons; icon indicates distribution of lesions on body; shape of medication, color). Absent some teaching or suggestion of the recited limitations, Applicants urged the Official Notice was an attempt at a hindsight reconstruction of the claim elements using the claims as the recipe, and requested that in the event the rejection is maintained the Examiner set forth document(s) teaching all of the recited limitations, and indicate the motivation for such a combination.

In response to Applicants noting of the failure of the rejection to set forth a disclosure of all of the recited elements and establish *prima facie* obviousness, the Examiner

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now seeks to reject the claims based upon the combination with a new reference, Kehr (U.S. Publ. 2003/0036683). Applicants maintain that in spite of the Examiner's urgings to the contrary in his remarks where he states that Kehr "does not result in a new issue," the Office Action at page 11, (¶ 14) sets forth a new grounds for rejection. Kehr is indeed a new reference cited to support the rejection, and a new ground for rejection not necessitated by any amendment by Applicants, and as a result of the new rejection <u>the finality of this action is premature</u>.
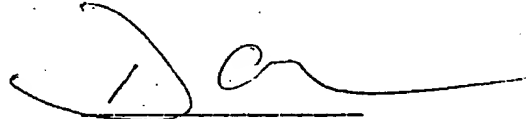
Furthermore, the Kehr publication is not available as a reference as it has a filing date (May 7, 2001) that is well after the earliest provisional application from which the instant application claims priority (e.g., Provisional Application No. 60/222,573, filed August 1, 2000, discloses the use of icons). In the event the rejection relies upon an earlier application by Kehr, Applicant respectfully requests that such an application be made of record. Otherwise, Applicants respectfully contend that Kehr is not available as a reference to suport the rejection, and that the rejection is also improper. Applicants respectfully traverse the rejection, request that the rejection be withdrawn, and that claims 16-18 and 20-21 be indicated as allowable in a subsequent action, or that in the event a rejection of these claims is re-asserted based upon another document, Applicants at least be permitted to offer amendments and remarks in response to such new grounds for rejection.

In view of the foregoing remarks and amendments, reconsideration of this application and allowance thereof are earnestly solicited. In the event that additional fees are required as a result of this response, including any fees for extensions of time, such fees should be charged to USPTO Deposit Account No. 50-2737 for Basch & Nickerson LLP.

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In the event the Examiner considers personal contact advantageous to the timely disposition of this case, the Examiner is hereby authorized to call Applicant's attorney, Duane C. Basch, at Telephone Number (585) 899-3970, Penfield, New York.

Respectfully submitted,

Duane C. Basch
Attorney for Applicant
Registration No. 34,545

Basch & Nickerson LLP
1777 Penfield Road
Penfield, New York 14526
(585) 899-3970

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